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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/528,989	03/20/2000	Jean Marie Vogel	9676-292	6000

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EXAMINER	
WANG, SHENGJUN	
ART UNIT	PAPER NUMBER
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/528,989	VOGEL ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,7,8,11-20,52,53 and 56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7-8, 11-20, 52-53, 56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on October 18, 2006 has been entered.

Claim Rejections 35 U.S.C. 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-4, 7, 8, 11-20, ~~and~~ 52, 53 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boschetti et al.

3. Boschetti et al. teaches the spherical particles herein and suspension composition comprising the same used for injection into tissue. The particles are made of hydrophylic acrylic co-polymer, and in preferred embodiment, with about 10% of bifunctional monomer. The particle sizes are range from 10 μm to 2000 μm. specific range of particle size within the range of 10 μm to 2000 μm are disclosed. See, particularly, the examples 1-21. The particles may be incorporated with other agents, such as dye, magnetic resonance imaging agent, or contrasting

agent. The particle s may also carry cell adhesion promoter. See, columns 3, lines 16-36, and the claims.

4. Boschetti et al. do not expressly disclose the polymer is anionic polymer, and the particular functions as herein recited. Boschetti also fails to expressly disclose the composition would be injectable through needles of about 26 to 18 gauge, or the particular amount of the particles in the composition, or the other particular agents in the composition as recited herein.

However, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to use anionic polymer as the hydrophilic polymer, such as polyacrylic acid salt, and to adjust the particle size within the disclosed range so that the composition would be suitable for injection with any needle required in the method.

5. A person of ordinary skill in the art would have been motivated to use anionic polymer as the hydrophilic polymer, such as polyacrylic acid salt, and adjust the particle size within the disclosed range so that the composition would be suitable for injection with any needle required in the method because it is disclosed that the composition should be injectable and acrylic polymer are known to be useful in the application. Anionic acrylic polymers is one of the three subgenus within the genus of acrylic polymers (the other two are neutral and cationic). It is noted that Boschetti et al. prefer neutrol or cationic polymers (col. 2, lines 11-16), but claim 1 encompasses all hydrophylic acrylic copolymers. It is well-settled that "Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971)." Note Further, employment of suitable carrier for an injectable composition, such as saline solution, would have been obvious to one of ordinary skill in the art because saline is a well-known

biocompatible carrier. Further, the incorporation of other well-known therapeutical agents, such as anti-inflammatory agents, or cells, with the particle would have been obvious since the other agents are known to be useful as therapeutical agents. As to the functional limitations, such as "swellable," "wherein the polymer can increase its weight by at least about 20 times its original dry weight upon contacting water", the examiner notes that since the reference teaches, or suggests all the limitations other than the functional properties, the polymer composition as suggested by the reference would reasonably be expected to have the same properties as herein claimed. When the reference discloses all the limitations of a claim except a property or function, *the burden is shifted to applicant* for proof that the subject matter as taught or suggested by the reference does not possess the function herein claimed. See *In re Fitzgerald,* 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

6. Claims 53 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boschetti et al. for reasons discussed above, and further in view of Tahara et al. (U.S. 5,298,570).

7. Boschetti et al. does not teach expressly the employment of sodium acrylate, and vinyl alcohol copolymers as the hydrophilic acrylic polymer.

8. Tahara et al. teach sodium acrylate/vinyl alcohol co-polymers are known hydrophilic biodegradable polymer. See, particularly, the example 6 in column 6 and the claims.

9. Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to use the sodium acrylate vinyl alcohol copolymers as the hydrophilic acrylic polymer.

A person of ordinary skill in the art would have been motivated to use the sodium acrylate vinyl alcohol copolymers as the hydrophilic acrylic polymer because hydrophilic acrylic

polymers are generally known to be useful, and sodium acrylate vinyl alcohol copolymers is particularly known as hydrophilic polymer. The employment of the copolymer is seen to be a selection from amongst equally suitable material and as such obvious. Ex parte Winters 11 USPQ 2nd 1387 (at 1388).

Response to the Arguments

Applicants' amendments and remarks submitted October 18, 2006 have been fully considered. The amendments and remarks are persuasive to the rejections under 35 U.S.C. 112 and 102 as set forth in the prior office action, but are not persuasive with respect to the rejections set forth above.

10. Boschetti teaches the employment of about 10% of bifunctional monomer, therefore would meet the limitation of "crosslinked in an amount of from about 0.5% to about 20%." As to the limitation of "swellable," "wherein the polymer can increase its weight by at least about 20 times its original dry weight upon contacting water", the examiner notes that since the reference teaches, or suggests all the limitations other than the functional properties, the polymer composition as suggested by the reference would reasonably be expected to have the same properties as herein claimed. When the reference discloses all the limitations of a claim except a property or function, *the burden is shifted to applicant* for proof that the subject matter as taught or suggested by the reference does not possess the function herein claimed. See *In re Fitzgerald,* 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

It is noted that Boschetti et al. preferred neutral or cationic polymers (col. 2, lines 11-16). However, it is well-settled that "Disclosed examples and preferred embodiments do not

constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971)."

As to claim 53, as well as claim 56, it is noted that Boschetti teaches generally the usefulness of acrylic polymers, Tahara discloses that the particular polymers herein are known and are biocompatible. Therefore, it would have been obvious to use the particular species within the genus. As to the remarks of "unexpected superior results", note a prima facie case of unexpected superior results residing in the claimed invention has not been established. As discussed above, no evidence on the record has shown that the composition disclosed by Bischetti does not possess the particular properties herein claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shengjun Wang
Primary Examiner
Art Unit 1617

S. Wang
SHENGJUN WANG
PRIMARY EXAMINER